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K080879 #4/6

G 510(k) SUMMARY

For the Bioretec ActivaPin™ Product Group

JUN 24 2008

MANUFACTURER

Bioretec Ltd.
Hermiankatu 22, Modulight Building
FI-33720 Tampere
FINLAND

Contact person:
Ms. Mari Ruotsalainen
Quality Manager
Phone: +358 20 778 9514
Fax: +358 3 317 0225
Mari.Ruotsalainen@bioretec.com

Date prepared: March 28th, 2008

DEVICE NAME

Trade Name: Bioretec ActivaPin™

Bioretec ActivaPin™ Fusion

Bioretec ActivaNail™ Conical

Bioretec ActivaNail™ Flat

Common Name: Pin, Fixation

ESTABLISHMENT REGISTRATION NUMBER

Bioretec Ltd. Establishment Registration Number is 3005536892.

DEVICE CLASSIFICATION AND PRODUCT CODE

Device Classification Name: Pin, Fixation, Smooth

Classification Panel: Orthopedic

Regulation Number: 21 CFR 888.3040

Product Code: HTY

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PREDICATE DEVICES

Bioretec ActivaPin™ (K061164)

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

Bioretec ActivaPin™ Product Group covers Bioretec's bioabsorbable devices ActivaPin™, ActivaPin™ Fusion, ActivaNail™ Conical and ActivaNail™ Flat.

The Bioretec ActivaPin™ products do not differ significantly or at all in purpose, design, materials, function or any other feature related to safety and effectiveness. ActivaPin™ is identical with a predicate device and the other devices of Bioretec's ActivaPin™ Product Group are its modifications. ActivaPin™ Fusion is the same as ActivaPin™, but its both ends are tapered. ActivaNail™ Conical and ActivaNail™ Flat are also ActivaPin™'s modifications with conical and flat heads. All pins of Bioretec ActivaPin™ Product Group are available in several different dimensions, including diameters of 1.5 – 3.2 mm and lengths of 5 – 70 mm.

The devices of Bioretec ActivaPin™ Product Group are indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.

The Bioretec ActivaPin™ Product Group devices are made of completely bioabsorbable poly(L-lactide-co-glycolide) (PLGA), and they degrade *in vivo* by hydrolysis into alpha-hydroxy acids that are metabolized by the body. As the operated bone fracture or osteotomy gains strength during healing, the Bioretec ActivaPin™ products gradually loses their strength, however, maintaining their function at least 8 weeks. Bioabsorption takes place within approximately two years thus eliminating the need for implant removal surgery.

EQUIVALENCE TO MARKETED PRODUCTS

The devices of Bioretec ActivaPin™ Product Group are substantially equivalent to the previously cleared Bioretec ActivaPin™ (K061164).

The Bioretec ActivaPin™ products have the same intended use and principles of operation, and also the same technological characteristic and performance as the previously cleared Bioretec ActivaPin™ (K061164). Any differences between Bioretec ActivaPin™ products and predicate device do not raise any questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2008

Bioretec Ltd.
% Ms. Mari Ruotsalainen
Hermiankatu 22, Modulight Building
FI-33720 Tampere
Finland

Re: K080879
Trade/Device Name: Activa™ Product group
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: March 28, 2008
Received: March 31, 2008

Dear Ms. Ruotsalainen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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F Indications for Use Statement

Submitter: Bioretec Ltd.

510(k) Number:

Device Name: ActivaPin™

ActivaPin™ Fusion

ActivaNail™ Conical

ActivaNail™ Flat

Indications for Use:

The devices of **Bioretec ActivaPin™ Product Group** including ActivaPin™, ActivaPin™ Fusion, ActivaNail™ Conical and ActivaNail™ Flat are indicated for fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080879